CLAIMS

1. An assay method for TSH-R autoantibodies or TSH, which method comprises step:

(a) contacting a test sample, in the presence or absence of TSH, with cells from a clone expressing human TSH-R transfected with a reporter construct comprising cDNA of both (i) a reactant, such as an enzyme, capable of causing a measurable response when brought into contact with a corresponding substrate, such as a protein, and (ii) a promoter containing cyclic AMP (cAMP) response elements (CREs), whereby cAMP levels vary with expression of the reactant.

2. An assay method according to claim 1, further comprising step:

(b) adding the corresponding substrate to cells thus contacted.

3. An assay method according to claim 2, further comprising steps:

(c) measuring the response in the cells exposed to the substrate; and

(d) comparing the response from test step (c) with the response from a standard or normal sample which has undergone steps (a) to (c).

4. An assay method according to any of claims 1 to 3, in which the measurable response is a colour change, fluorescence change or emission of light.

5. An assay method according to claim 4, wherein the reactant is selected from chloramphenicol acetyl transferase (CAT), Firefly luciferase, R nilla luciferase, β-galactosidase, alkaline phosphatase, horseradish

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peroxidase and green fluorescent protein.

6. An assay method according to any preceding claim, wherein the cyclic AMP response element (CRE) of the reporter construct comprises a promoter sequence or synthetic oligonucleotide which contains the CRE consensus sequence, TGACGTCA.

7. An assay method according to claim 6, wherein the cyclic AMP response element (CRE) comprises a tandem repeat of the CRE consensus sequence, TGACGTCA.

8. An assay method according to any preceding claim, wherein the promoter is that for the glycoprotein hormone alpha subunit that contains tandem cAMP response elements.

9. An assay method according to any of claims 1 to 6, wherein the promoter comprises a construct driving the CAT enzyme.

10. An assay method according to claim 3, which comprises, in step (a), the use of a luciferase cDNA driven by a promoter containing cAMP response elements; in step (b), the use of luciferin; and, in step (c), measuring the light output from the luciferinised cells.

11. An assay method according to any preceding claim, wherein the reporter construct comprises α-luciferase.

12. An assay method according to any preceding claim, wherein all reagents used therein are brought together in one or more steps; and/or wherein two or more of the steps (a) to (d) are carried out substantially simultaneously.

13. An assay method according to any preceding claim, which is carried out by manual, partly automated or fully automated means.

14. A kit for carrying out an assay according to any preceding claim.

15. A kit according to claim 14, which kit comprises:

(a) cells from a clone expressing human TSH-R transfected with a reporter construct comprising cDNA of both a reactant, such as an enzyme, capable of causing a measurable response when brought into contact with a corresponding substrate, such as a protein, and a promoter containing cyclic AMP (cAMP) response elements (CREs), whereby cAMP levels vary with expression of the reactant;

(b) a standard sample for the assay;

(c) medium for culturing and/or reconstituting the cells; and

(d) instructions for carrying out the assay.

16. A kit according to claim 15, further comprising:

(e) buffer for lysing the cells; and/or

(f) buffer for the reporter construct, preferably luciferase buffer; and/or

(g) corresponding substrate, preferably luciferin, in buffer;

and, optionally, a luminometer.

17. A kit according to any of claims 14 to 16, wherein the reporter construct comprises the plasmid pA3luc having the glycoprotein hormone α subunit promoter introduced therein.

18. A kit according to any of claims 14 to 17, wh rein the CRE-containing

sequence is sub-cloned into a commercially-available luciferase reporter system, such as pGEM-luc.

19. A kit according to any of claims 14 to 17, wherein the reporter construct comprises a plurality of plasmids.

20. A kit according to any of claims 14 to 17, wherein the human TSH-R is sub-cloned into a eukaryotic expression vector.

21. A kit according to claim 20, wherein said eukaryotic expression vector is pSVL.

22. A kit according to claim 20, wherein the TSH-R is sub-cloned into a dual vector that incorporates the antibiotic resistance gene within the same plasmid.

23. A kit according to claim 22, wherein the dual vector comprises pcDNAIII.

24. A kit according to any of claims 14 to 23, wherein the cells for component (a) are from clone JP09 as identified herein, which have been stably transfected within the order of 10^5 TSH-R per cell.

25. A kit according to claim 24, wherein said cells are co-transfected with both α-luciferase cDNA and a puromycin resistance encoding plasmid.

26. A kit according to any of claims 14 to 25, wherein the cells are lyophilised (freeze-dried), frozen or comprised in a gel, and provided in individual containers.

27. A kit according to any of claims 14 to 25, wherein said cells are further co-transfected to provide the assay with a method of correcting for the number of cells seeded in a well during use.

28. A kit according to claim 27, wherein said cells are further co-transfected using a Renilla luciferase plasmid.

29. An assay method or a kit according to any preceding claim for use in association with a condition or disease selected from: autoimmune thyroid disease, non-autoimmune thyroid disease, autoimmunity of non-thyroid origin and polyendocrine disease.

30. An assay method or a kit according to any preceding claim for use in screening patients selected from: pregnant women, those with euthyroid eye disease, and those receiving amiodarone and/or lithium.

31. An assay method or kit according to any preceding claim for measuring TSAb or TBAb, or for measuring autoantibodies to the TSH-R having part of its sequence modified, such as by having one or more of its amino acids replaced or otherwise modified to include tags.

32. A reporter construct comprising cDNA of both a reactant, such as an enzyme, capable of causing a measurable response when brought into contact with a corresponding substrate and a promoter containing cAMP response elements, whereby increased cAMP levels vary with expression of the substrate.

33. A reporter construct according to claim 32 wherein the reactant enzyme is a luciferase.

34. A clone expressing human TSH-R transfected with a reporter construct according to claim 32 or claim 33.

35. Cells produced by a clone according to claim 34.

36. cDNA or mRNA expressing human TSH-R transfected with a reporter construct according to claim 32 or claim 33.

37. Human TSH-R transfected with a reporter construct comprising cDNA of both a reactant, such as an enzyme, capable of causing a measurable response when brought into contact with a corresponding substrate, such as a protein, and a promoter containing CRE.